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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

RANCHERS CATTLEMEN ACTION LEGAL FUND UNITED STOCKGROWERS OF AMERICA, Plaintiff, vs. UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, et al., Defendants.	Cause No.CV-05-06-BLG-RFC **MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION TO SET MOTIONS FOR SUMMARY JUDGMENT FOR ARGUMENT**

The Court's order of July 20, 2005 canceling the scheduled argument on the cross-motions for summary judgment in this case stated that the Court would "determine whether further hearings are necessary" after receipt of the Ninth Circuit's opinion on the U. S. Department of Agriculture ("USDA's") appeal of the preliminary injunction issued March 2, 2005. (That opinion was issued on July 25, 2005, 415 F.3d 1078.) In response to the implication in the July 20th order that the Ninth Circuit opinion on the preliminary injunction appeal could obviate the need for further proceedings, Ranchers Cattlemen Action Legal Fund United Stockgrowers of America ("R-CALF USA") explains below why the Ninth Circuit's action and opinion should have no effect on R-CALF USA's opportunity for a hearing on, and full consideration of, its motion for summary judgment.

I. THE NINTH CIRCUIT'S DECISION VACATING THE PRELIMINARY INJUNCTION DOES NOT LIMIT OR ELIMINATE THE NEED FOR ARGUMENT AND A RULING ON THE SUMMARY JUDGMENT MOTIONS.

Fed. R. Civ. P. 56(b) contemplates that a hearing will be held on a motion for summary judgment. The fact that a preliminary injunction was issued in this case and then vacated by the Court of Appeals does not eliminate the need for that hearing.[1] (In this case, since no witnesses will be called, the parties and the Court anticipated that the hearing would consist of oral argument by counsel.) Obviously, the Court of Appeals was reviewing an interlocutory order that did not purport to resolve the merits of the case and that was entered before the merits of the case had been fully briefed.

Actions related to a preliminary injunction do not bind the district court with respect to a decision on the merits. Wright and Miller, *Federal Practice and Procedure*, Section 2962, 437-

[1] Under Fed. R. Civ. P. 65(a)(2), a district court judge may order the trial on the merits accelerated and consolidated with the preliminary injunction hearing, but that did not happen in this case, and indeed extensive briefing on the merits occurred after the preliminary injunction hearing.

438 (2004), observes that the decision of both the trial and appellate court on whether to grant or deny a preliminary injunction does not preclude the parties in any way from litigating the merits of the case. The Ninth Circuit has reiterated that self-evident proposition, stating in *City of Anaheim, Calif. v. Duncan*, 658 F.2d 1326, 1328, n.2 (9th Cir. 1981) that "we have not departed from the general rule that a decision on a preliminary injunction does not constitute the law of the case and the parties are free to litigate the merits." (Citations omitted.) In *Ross-Whitney Corp. v. Smith, Kline and French Labs*, 207 F.2d 190,194 (9th Cir. 1953), for example, the Ninth Circuit held that a "ruling on the motion for a preliminary injunction leaves open the final determination of the merits of the case."

Even if that precedent did not exist, however, it is clear under the circumstances of this case that the Ninth Circuit's action on USDA's appeal of the preliminary injunction issued against it could not dictate the resolution of, nor eliminate the opportunity for a hearing on, R-CALF USA's motion for summary judgment. One of the grounds on which the Ninth Circuit vacated the preliminary injunction—that this Court supposedly did not properly assess the balance of harms from an injunction (415 F.3d at 1093)—is entirely irrelevant to a decision whether to accept R-CALF USA's claim that the Final Rule was issued in violation of the Administrative Procedure Act (APA). The APA does not require any balancing of the harms before a court determines that a regulation should be vacated under 5 U.S.C. § 706(2).

The other grounds for the Ninth Circuit's decision, that the District Court erred in deciding that R-CALF USA was likely to succeed on the merits, necessarily related only to the facts that had been presented at the time of the preliminary injunction hearing. The presentation of the issues at the preliminary injunction stage was understandably limited, both in terms of the issues presented and legal arguments made and in terms of the factual support for those

arguments. Indeed, USDA had not yet even completed and filed with the Court and with R-CALF USA its index of and copies of materials in the Administrative Record at the time that R-CALF USA filed its memorandum in support of its application for a preliminary injunction. After this Court issued the preliminary injunction, USDA purported to amend the Administrative Record, adding both documents that were available prior to the preliminary injunction hearing but had not been identified to the Court and R-CALF USA and also documents that were not even in existence when the preliminary injunction was issued. Additionally, R-CALF USA has called to the Court's attention a number of more recent documents, of which the Court may take judicial notice, that further support R-CALF USA's claims.

Thus, it would have been impossible as a practical matter for the Ninth Circuit to resolve all of the issues presented by the cross-motions for summary judgment, even if it had been legally authorized to do so in a preliminary injunction appeal. This Court now must consider all of the evidence and arguments presented in the summary judgment proceedings.

II. NUMEROUS ISSUES REMAIN TO BE ADDRESSED IN A HEARING AND DECISION ON THE SUMMARY JUDGMENT MOTIONS.

The Court of Appeals reversed the preliminary injunction because it concluded that this Court committed legal error by failing to respect USDA's judgment and expertise. 415 F.3d at 1093-94. (It also concluded—incorrectly, R-CALF USA believes—that this Court improperly imposed on USDA a requirement that its actions present a zero risk to human health.[2]) But as

[2] 415 F.3d at 1094-95. (Indeed, it is USDA that claims that "the risk of BSE from Canadian beef is next to zero." Defendants' Memorandum in Support of Summary Judgment at 12.) In disposing of that straw man, the Ninth Circuit opinion concluded that the Animal Health Protection Act "does not require the Secretary to quantify a permissible level of risk or to conduct a risk assessment." *Id.* at 1097. But the panel apparently was unaware that USDA's own procedures for evaluating whether to allow imports from a particular region that potentially carry a pest or disease, AR009519-29, state that, while a qualitative risk analysis is generally adequate for regions considered free of certain diseases, regions in which the disease is known to exist due

numerous decisions of the Supreme Court and the Ninth Circuit, cited in R-CALF USA's Memorandum in Support of Summary Judgment and its Reply Memorandum, have held, the principle of deference to an administrative agency's expertise does not require or even permit blind acceptance of the agency's conclusions. The Ninth Circuit's opinion vacating the preliminary injunction in this case recognizes that, as well. *Id.* at 1093 and 1095 n.15.

The presumption in favor of agency expertise is overcome if, for example, the agency "has relied on factors which Congress has not intended it to consider," if it "entirely failed to consider an important aspect of the problem," or if it "offered an explanation for its decisions that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of the agency expertise." *Id.* Providing an internally inconsistent justification for a rule is another reason the agency's decision may be found arbitrary and capricious, despite the agency's expertise, since the decision therefore was "not founded on a reasoned evaluation of the relevant factors." *Defenders of Wildlife v. U.S. EPA*, 420 F.3d 946, 959 (9th Cir. 2005) (citations omitted). Additionally, the Ninth Circuit opinion vacating the preliminary injunction did not overturn, nor could it, the established principle that an agency

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to recent outbreaks are deemed to pose a higher level of risk and have historically been approached quantitatively. AR009525. This is because "[q]uantitative modeling allows assessment of specific risk concerns, testing of assumptions, analysis of attendant uncertainty, and evaluation of the effectiveness of proposed mitigation measures." *Id.*; *accord,* PL 107-9 Interagency Working Group Report, AR009309 ("need to update risk assessments" when "BSE cases are confirmed in other countries"); *see also* Declarations of Drs. Cox and Charnley attached to R-CALF USA's Reply Memorandum. The panel also apparently was unaware of the Animal Disease Risk Assessment, Prevention, and Control Act of 2001, P.L. 107-9, which reflects Congress' desire "to make certain that the Congress and the American public are fully informed as to the reliability of our nation's animal health inspection system, its ability to protect our domestic herds and the American public from the potential introduction into the United States of" BSE. 147 Cong. Rec. S3709 (April 6, 2001); *see also* P.L. 107-9 sec. 2(b) (purpose to provide the public with information on public health risks of BSE). Because the panel's analysis did not address these considerations, this Court is not bound by their conclusion that no quantification of the risk of such a major, precedent-setting action as the Final Rule is needed.

must provide a reasoned explanation for its departure from a past factual determination or policy determination, rather than simply changing its mind. *See* R-CALF USA's Memorandum in Support at 6-7; *see also, e.g., California v. FCC*, 905 F.2d 1217, 1234 (9th Cir. 1990); *Lynch v. Dawson*, 820 F.2d 1014, 1021 (9th Cir. 1987).

These criteria for judicial review of agency actions must be applied to the full set of facts presented to the Court in the cross-motions for summary judgment and supporting materials. As noted above, the Ninth Circuit panel that vacated the preliminary injunction could not possibly have done so. To the extent that its opinion might be read to suggest otherwise (*cf.* 415 F.3d at 1100), such an interpretation would be misplaced, and in any event it would not be binding on a determination by this Court of the merits of the case, as noted above.[3]

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[3] Additionally, in many respects the Ninth Circuit panel's decision simply got the facts wrong—understandable in light of the limited time available and the incomplete development of the facts at the time. For example, the opinion refers to the feed ban as historically USDA's "first and foremost" measure for preventing BSE in the United States, when USDA's 2003 report to Congress and other official statements clearly show that the most important line of defense has been restrictions on importation of infected cattle and beef. *Cf.* 415 F.3d at 1087 *with* Memorandum in Support at 6-7 and AR009261, AR009267. *See also* 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997) (given the lack of a vaccine or a test to detect the disease in live animals, banning imports of cattle and beef is "the most effective means available for ensuring that BSE does not enter the United States...."); AR009307. The opinion mistakenly referred to the Harvard Study's conclusion that SRM removal would reduce human exposure by 95% as if it addressed the risk from the Final Rule (*see* 415 F.3d at 1099), when in fact the Harvard Study referred to the much more extensive SRM requirements that apply in the United Kingdom to both human and animal food. *See* Harvard 2003 study at AR003736, AR003737, AR003809; *cf.*70 Fed. Reg. at 467 (AR008051). The panel seemed to think that the Final Rule would not result in the importation of infected cattle because only Canadian cattle under 30 months of age can be imported and BSE is rarely detected in animals of that age, *see* 415 F.3d at 1095, apparently unaware that infection likely begins early in life and that, as the latest version of the OIE Terrestrial Animal Health Code now explicitly recognizes, in fact the majority of infected animals in a country with BSE cannot be detected through either observation or post-mortem testing. *See* Exhibit 1 to R-CALF USA's Reply Memorandum, at Article 3.8.4.1 (2). The opinion took comfort in the fact that no cases of vCJD have been attributed to eating domestic beef in the U.S. or Canada, 415 F. 3d at 1097, but apparently based on a misunderstanding of the relationship between consumption of contaminated meat and displaying symptoms of vCJD: the panel stated that the vast majority of vCJD cases occurred in England during the height of the

The Ninth Circuit opinion did not address, for example, the evidence indicating that USDA considered inappropriate factors, such as a desire to have open trade with Canada and the expressed financial impact on multinational meat packers, as discussed in R-CALF USA's Memorandum in Support of Summary Judgment at 7-10. The briefing in this case revealed numerous examples of how preconceived outcomes dictated the results of USDA's BSE mitigation measures for Canada. Deference to agency judgments is not warranted in such cases. *See, e.g., Entergy Ark., Inc. v. Nebraska*, 210 F.3d 887 (8th Cir. 2000) (where state reached political conclusion before facts were available, no deference given to its factual conclusions); *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual,* 463 U.S. 29, 52-56 (1983) (no deference when agency emphasized cost of automatic seatbelts in contrast to congressional intent that passenger safety be primary concern).

The conclusion that USDA's regulation of BSE has been guided by consideration of inappropriate factors rather than sound scientific judgment is reinforced by a very recent USDA action (of which this Court can take judicial notice, and of which the Ninth Circuit panel was obviously unaware): On December 14, 2005, 70 Fed. Reg. 73,905 (attached as Exhibit 1), USDA authorized imports of beef from Japan, without regard to the age of the cattle at the time of slaughter and despite the fact that Japan only enacted a ruminant-to-ruminant feed ban in late 2001. *See id.* at 73,917-18 and 70 Fed. Reg. 48,494 (Aug. 18, 2005) (attached as Exhibit 2). Yet Japan clearly has a BSE problem, having found 21 cases of BSE among a national adult cattle population of only about 2 million head, some of which were born after Japan's feed ban and the latest of which was discovered only this month. See APHIS, "Analysis of Bovine Spongiform

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BSE epidemic, when in fact the very first case of vCJD was not detected until 3-4 years after the height of the BSE epidemic in the UK. *Cf.* 415 F.3d at 1096-97 *with* 70 Fed. Reg. at 462 (AR008046). This Court is under no obligation to follow such premature and incorrect statements of the facts.

Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan" (attached as Exhibit 3), at 7, 14; O.I.E. report available at http://www.oie.int/eng/info/en_esbmonde.htm. The fact that USDA now asserts that importing beef from Japan is safe--even though Japan has not implemented the minimal preventive measures USDA determined less than a year ago are necessary for imports of beef from Canada, and without any new scientific information indicating that the threat of BSE is less than previously believed--is stark evidence of USDA's willingness to twist the facts to support its trade-related ends.

Furthermore, in this latest Federal Register publication, USDA itself acknowledges that it should not be basing its decisions about whether to restrict imports of cattle or beef from countries with BSE on the potential impacts on trade: "APHIS does not have authority to restrict trade based on its potential market access effects. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article when the agency determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock." 70 Fed. Reg. at 73,914; *see also id.* at 73,916. This is directly contrary to USDA's actions with respect to BSE and imports from Canada. As R-CALF USA has noted previously, the Administrator of APHIS authorized permits for the importation of ground beef from Canada because certain industry groups asserted APHIS policy banning ground beef as too risky was "too restrictive for trade." *See* R-CALF USA's Memorandum in Support at 10 n.6 and AR010549.

The Ninth Circuit panel that vacated the preliminary injunction did not address at all the fact that USDA reversed its judgment about measures necessary to prevent the introduction of BSE into the United States, without providing adequate justification and without referencing new information that could justify reversing its position. The principal device that USDA now claims

will provide adequate protection to U.S. cattle if BSE-infected cattle are imported from Canada, the prohibition on feeding ruminant protein to other ruminants, has been in place since 1997. 70 Fed. Reg. at 466 (AR008050). Yet USDA has said repeatedly since then that, because of the unique nature of BSE, importation and rendering of BSE-infected cattle, followed by misfeeding to U.S. cattle, is one of the primary risks for introduction of BSE into the United States, and a ban on imports from all countries with BSE is an essential defense.[4] The "Harvard Study" on which USDA principally relies for support in its relaxation of BSE protections for Canada, was first completed in 2001 and relies on scientific studies reported primarily in the 1990s. *See, e.g.*, 70 Fed. Reg. at 466-67 (AR008050-51); AR001783-84. Thus, it does not appear that USDA is now relying on new information that was unavailable when USDA in recent years repeatedly reaffirmed the importance of the ban on imports of cattle from BSE-afflicted countries. (In fact, as noted in previous briefing and below, new scientific information should be leading USDA to more caution about BSE, not less.) This Court still must determine whether, in light of those facts, USDA has justified its departure in the Final Rule from previous determinations.

III. RECENT DEVELOPMENTS REINFORCE R-CALF USA'S CONTENTIONS AND CONFIRM THAT USDA'S ACTIONS WARRANT THIS COURT'S CAREFUL, CRITICAL REVIEW.

Since briefing on the cross-motions for summary judgment was completed, there have been additional USDA and FDA actions as well as the publication of new scientific data, both of which further support the arguments R-CALF USA made in briefing its motion for summary judgment. In some cases, these developments provide further support for concerns this Court

[4] *See, e.g.*, 66 Fed. Reg. 52,483 Oct. 16, 2001 ("emergency" interim rule banning imports from Japan, affirmed at 67 Fed. Reg. 8181 (Feb. 22, 2002)); 56 Fed. Reg. 63,865, 63,867-68 (Dec. 6, 1991); 62 Fed. Reg. 65,747, 65,748 (Dec. 16, 1997). USDA also repeatedly praised Canada's policy of banning imports of cattle from all countries where BSE is known to exist as a key measure reducing Canada's BSE risk. *See, e.g.*, 70 Fed. Reg. at 464, 467, 486 (AR008048, AR008051, AR008070); 70 Fed. Reg. 18,252, 18,254 (April 8, 2005).

already identified during the preliminary injunction proceedings. They further emphasize the need for argument and a decision on the merits of R-CALF USA's claims.

Most recently, USDA promulgated a rule, first referenced above, allowing importation of boneless cuts of beef from cattle born, raised, and slaughtered in Japan, without regard to the age of the animal at time of slaughter, and despite the fact that Japan has a real, current BSE problem (the "Japan Rule"). See pp. 7-8, *supra*. In addition to demonstrating even more clearly that USDA's approach to the regulation of BSE is not consistent with its statutory obligations to protect the U.S. cattle herd and U.S. consumers from the introduction of BSE into the United States, the Japan Rule contains numerous statements that are inconsistent with USDA's statements in support of the Final Rule concerning Canadian imports at issue here. A regulation supported by "internally contradictory agency reasoning," as well as decisions "inconsistent with the governing statute," must be struck down under the Administrative Procedure Act. *Defenders of Wildlife*, 420 F.3d at 959.

The Japan Rule effectively concludes that SRM removal measures are the only BSE mitigation steps necessary to protect U.S. consumers from importation of beef from a country whose cattle have a significant risk of BSE infection. In the present case, USDA has responded to R-CALF USA's numerous demonstrations that USDA's assumptions about the effectiveness of SRM removal are unproven and unfounded primarily by claiming that SRM removal results in a substantial reduction of the risk of BSE that, when combined with other "overlapping" BSE mitigation measures required by the Final Rule, results in an insignificant risk to consumers. USDA never claimed in the instant case that SRM removal alone was sufficient to protect against unacceptable risks of vCJD; in fact, USDA acknowledged that SRM removal might reduce the

risk by only 80%. *See, e.g.*, Englejohn Declaration I at 8; *but cf.* 70 Fed. Reg. at 467 (AR008051) (SRM removal reduces human exposure by 95%).

In the Japan Rule, dealing with a country whose cattle appear more likely to be infected with BSE than Canada's, USDA now asserts that limiting beef only to that from cattle under 30 months of age (UTM cattle) and most other mitigation measures on which the Final Rule was based are unnecessary so long as SRM removal occurs. The preamble to the Japan Rule provides no real answer to comments that pointed out these inconsistencies. *See id.* at 73,913 and 73,915. These inconsistent rationales, coming within less than a year of one another, indicate the arbitrary nature of USDA's conclusions about the risk of Canadian imports.

The preamble to the Japan Rule contains a dramatic inconsistency with a rationale for the Final Rule on Canadian imports. In setting forth the criteria for qualification as a BSE minimal-risk region, the Final Rule preamble states that a region must maintain and, if BSE has been detected, have had in place prior to the detection of BSE, "risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:" One of the three risk mitigation measures listed is: "surveillance for BSE at levels that meet or exceed recommendations of the [O.I.E.] for surveillance for BSE." 70 Fed. Reg. at 463 (AR008047). Yet in the Japan Rule, USDA takes a completely different position:

> ...we do not consider the testing of bovines at slaughter to be scientifically justified or meaningful in the context of either human or animal health. Making this a criterion for the importation of beef from Japan would not contribute to human or animal health protection. A statistically and epidemiologically valid surveillance plan is crucial to monitoring the success of risk mitigation measures, such as a feed ban, but *surveillance is not a mitigation measure.*

70 Fed. Reg. at 73,914 (emphasis added). No new scientific information is offered as the basis for that complete about-face. When USDA makes such an entirely inconsistent statements about

a key aspect of BSE mitigation, it has by definition produced an arbitrary and capricious rule that must be remanded for further explanation.

R-CALF USA has documented, in its comments on the Proposed Rule and its submissions to the Court, numerous inadequacies in the current ruminant-to-ruminant feed bans in place in the United States and Canada. USDA has assumed that these feed bans are highly effective, despite the known loopholes. In the preamble to the Final Rule, USDA dismissed concerns about the effectiveness of the U.S. feed ban by saying that the Food and Drug Administration (FDA) planned to address these loopholes in the future. *See, e.g.*, 70 Fed. Reg. at 532 (AR008116), 504 (AR008088); USDA Response to IRT Report at AR008040. FDA has now proposed amendments to the U.S. feed ban, and that proposal reinforces many of the concerns that R-CALF USA has expressed about the feed ban and that USDA has ignored.

The proposed amendments to the feed ban, 70 Fed. Reg 58,569 (Oct. 6, 2005) (Exhibit 4) (the "feed ban amendments"), do not remove all of the loopholes that USDA had left in the Final Rule for FDA to address. *Cf.* feed ban amendments with 70 Fed. Reg. at 504 (AR008088). FDA does acknowledge, however, the validity of numerous issues about potential ineffectiveness of the feed ban that R-CALF USA raised in its comments on the proposed USDA rule and in briefing in this case. For example:

> European experience showed that, in countries with high levels of circulating BSE infectivity, controls on only ruminant feed were not sufficient to prevent further transmission of BSE. Until SRMs were removed from all animal feed, a significant number of new cases continued to be found in cattle born in the United Kingdom after implementation of a ruminant-to-ruminant feed ban (Ref. 12). These new cases were attributed to either cross-contamination during feed manufacture and transport, or to intentional or unintentional misfeeding on the farm.

70 Fed. Reg. at 58,577. FDA states that it has been concerned about cross-contamination due to inadequate clean out procedures at feed mills that process both ruminant feed and non-ruminant

feed, and that recent data indicating that BSE-infected tissue may be an even more potent infectious agent than previously thought heightens that concern. *Id.*; *cf.* R-CALF USA's Memorandum in Support at 19 nn. 10, 11. FDA recognizes the potential for noncompliance with the existing feed ban regulations by manufacturers and distributors and notes that there have indeed been numerous incidents of noncompliance. While noncompliance has typically been corrected by the firms involved, "the occurrence of these deficiencies nonetheless supports the need for additional measures to address concerns about the presence of high-risk materials in the non-ruminant feed supply." 70 Fed. Reg. at 58,577. FDA also expressed its concern about intentional and unintentional misfeeding of non-ruminant feed to ruminants on the farm, recognizing that "[a]ssuring that misfeeding does not occur on the farm is particularly difficult due to the large number of cattle feeding operations in the United States, and FDA's extremely limited resources to inspect these operations, which number over 1 million." *Id.* at 58,578.

These very recent statements by the federal agency responsible for implementing the feed ban confirm R-CALF USA's assertions in this case that it was arbitrary and capricious for USDA to conclude that there is virtually no risk of BSE-contaminated tissues from Canadian cattle entering the U.S. ruminant feed supply.[5] Additionally, the preamble to the feed ban amendments reveals another glaring inconsistency, if not outright deception, in USDA's support for the Final Rule. The preamble refers to a modification that USDA made to the Harvard-Tuskegee model, estimating that the interim final rules published by USDA FSIS (requiring SRM removal) and by

[5] *Cf.* R-CALF USA Memorandum in Support at 15-20. The feed ban amendments also provide further support for R-CALF USA's estimate of the BSE infection rate in Canada in light of the rate in the targeted animals tested so far: FDA says that in the EU cattle slaughtered because of health problems are 100 times more likely to test positive for BSE than apparently healthy cattle, while "downers" are 20 times more likely. (The ratios from Swiss data are 58 and 49 times, respectively.) 70 Fed. Reg. at 58,578; *cf.* 415 F.3d at 1097 (calling Dr. Cox's assumption that the distressed cattle tested by Canada are 60 times more likely to have BSE than apparently healthy cattle an "unexplained assumption").

FDA (partial feed ban) "reduced human exposures to infectious materials by an average of 80 percent." 70 Fed. Reg. at 58,587, citing "Ref. 26," an April 7, 2004 USDA report. Yet USDA claimed in the Final Rule, and represented to the Ninth Circuit, that banning SRMs from human and animal food reduces human exposure to BSE by 95 percent, based on the 2003 Harvard Study! *See* 70 Fed. Reg. at 467 (AR008051); 415 F.3d at 1099. Omitting this April 7, 2004 revised modeling from the Administrative Record for the Final Rule does not insulate USDA's decision from being arbitrary and capricious for relying on outdated and inconsistent modeling.

Concerns about the feed ban previously raised by R-CALF USA have been reinforced as well by a recent Government Accountability Office report on FDA's administration of feed testing to determine potential for contamination with BSE. *Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 with Recommendations for Making the Program a Better Oversight Tool*, October 11, 2005 (GAO Report) (attached as Exhibit 5). Once again, GAO concludes that FDA lacks sufficiently robust data to allow it to reach conclusions about the effectiveness of the feed ban.[6] The test data that do exist confirm R-CALF USA's previous concerns: for example, in May 2004 FDA reviewed 370 feed samples taken in the first 8 months of the testing program and identified 70 samples classified by laboratories as potentially in violation of the feed ban, including 42 samples of feed intended for cattle. Id. at 13. The GAO Report also reiterates that the incubation period for vCJD may be as long as 30 years (Exhibit 5 at

[6] *Id.* at 7. GAO reports on feed ban enforcement and compliance that R-CALF USA previously cited concluded that the feed ban compliance data relied on in the Harvard Risk Assessment and derived from FDA's inspection database was "so severely flawed that the agency could not know the extent of industry noncompliance." Exhibit 4 to R-CALF USA Memorandum in Support of Summary Judgment, at p. 4; *see also id.* pp. 5, 30 ("we believe FDA is overstating the industry's compliance with the animal feed ban and understating the potential risk of BSE for U.S. cattle in its reports to Congress and the American people"), and AR009217, AR009232. (Note that the reference in the text of R-CALF USA's Memorandum in Support contained a typo, referring to the Feb. 2005 GAO report as Exhibit 1 rather than Exhibit 4. *See* Memorandum in Support at 19.

5), further undermining USDA's claim that Canadian and U.S. BSE mitigation programs have been proven effective because there are no confirmed cases of vCJD related to human exposure in Canada or the U.S. …yet. *Cf.* Defendants Reply in Support of Summary Judgment, at 10.

Both the Japan Rule and the feed ban amendments provide data flatly contradicting USDA's assertions in this case that testing of apparently healthy cattle is of no value: FDA explains that the EU continues to identify BSE cases in healthy animals under its mandatory testing regime, reporting in the preamble to the feed ban amendments that the EU is identifying BSE cases at a rate of 1 positive animal per 32,258 healthy slaughter animals tested. 70 Fed. Reg. at 58578. And according to the USDA risk analysis accompanying the Japan Rule, a majority (11 of 20) of confirmed BSE cases in Japan were detected only through mandatory testing of cattle without clinical signs of BSE. *See* Exhibit 3 at 8, Table 1. *Cf.* Fox, et al., AR001575 (BSE found in about 1 per 25,000 apparently healthy cattle tested in Europe).

There have been numerous other developments that have confirmed R-CALF USA's demonstrations that USDA erroneously assumed, without data or in contradiction to the data, that the BSE mitigation measures in the Final Rule would be sufficient to "virtually eliminate" the risk from BSE-infected Canadian cattle.

Despite USDA's assurances to the Court that there was an "impenetrable barrier" to BSE from imports, within three weeks after the Final Rule went into effect an animal exceeding the 30-month limit was imported from Canada into the United States. Moreover, it was slaughtered in the United States and, despite USDA's assurances that high-risk materials will not enter the human food supply, the animal was processed with its spinal column and other SRM tissues

intact. The meat was not recalled until more than two weeks after it was produced.[7] Media reports indicated that USDA did not know how much meat may have been consumed after it was distributed to six states.[8] Furthermore, that same shipment from Canada was discovered to have contained eight pregnant heifers, confirming the concern raised by this Court that the Final Rule "does not prohibit cattle of breeding age from being bred either before or after entering the U.S." *R-CALF I*, 359 F. Supp. 2d 1058, 1069. The known importation of pregnant heifers also belies the Ninth Circuit conclusion that this Court's concerns are unjustified because "USDA has made it abundantly clear that cattle may not be imported for breeding under the new regulations." 415 F.3d at 10848. The Final Rule, as R-CALF USA asserted and as the facts have now proven, does not prohibit importation of pregnant cattle, despite the statement in the preamble of the Final Rule that "[b]reeding cattle of any age may not be imported into the United States from Canada under this rule." 70 Reg. at 515 (AR008099). These developments demonstrate empirically the legitimacy of R-CALF USA concerns of potential for BSE exposure that USDA assumed away.

Similarly, data obtained by Public Citizen through a Freedom of Information Act request uncovered more than 1000 violations of BSE mitigation measures at slaughterhouses inspected by USDA's Food Safety and Inspection Service over an 18-month period, confirming comments by R-CALF USA and others that SRM removal policies were not being implemented comprehensively. *See* AR001637-38. An analysis of 829 BSE-related noncompliance reports from January 2004 to March 2005 showed that about one-third of the citations were for improper

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[7] *See* USDA FSIS Recall Notification Report 032-2005, available at http://www.fsis.usda.gov/Fsis_Recalls/RNR_032_2005/index.asp.

[8] Associated Press, "Beef Abandoned Under Mad Cow Rules Is Recalled," (Aug. 23, 2005), available at http://www.sunherald.com/mld/sunherald/news/breaking_news/12447370.htm; *see also* Reuters, "Canada Violates US Mad Cow Rules, Ships Adult Cow "(Aug. 23, 2005), available at http://www.planetark.com/dailynewsstory.cfm/newsid/32138/story.htm (a total of 15 pregnant heifers had been imported in five shipments).

removal or handling of SRMs. Almost 10% of the citations were for animals 30 months of age or older that were identified as UTM and therefore were not subjected to SRM removal requirements (aside from tonsils and distal ileum). Public Citizen, "BSE Noncompliance Record Analysis," available at http://www.citizen.org/cmep/foodsafety/madcow/articles.cfm?ID=13903.[9] The Harvard Risk Assessment assumed that even the far more comprehensive SRM removal practices of the United Kingdom would not be 100% effective in eliminating potentially BSE-infected tissue from food, but it did not consider at all the effect of substantial noncompliance, in which SRM removal does not take place at all. *See* AR003808-309, AR003794 (UK-type SRM ban "eliminates the potential" for SRM tissues "to contaminate either human food or rendered material that might be used in feed"), AR013634 (model assuming SRM ban has zero possibility of brain, spinal cord, etc. entering human food supply). The actual results of USDA/FSIS inspections confirm R-CALF USA's allegations and demonstrate dramatically the inadequacy of the risk assessment's assumptions about the effectiveness of SRM removal. Such assumptions that are contradicted by facts known to the agency render its decision arbitrary and capricious. *See* cases cited in R-CALF USA's Memorandum in Support of Summary Judgment at 5, 15.

Scientific developments have continued to occur rapidly with respect to BSE, and, in stark contrast to USDA's cavalier response to the BSE problem, those scientific developments have only accentuated the need for greater care in the nation's BSE protection program. Importantly, new information tends to support previous studies, cited by R-CALF USA in the

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[9] *See also* "Mad-Cow Rule Breaches By Meat Packers Are Noted," *Wall Street Journal* (Aug. 19, 2005) at C5; "Meat Industry Ignores Mad Cow Regulations," consumeraffairs.com (August 19, 2005), available at http://www.consumeraffairs.com/news04/2005/mad_cow_pubcit.html; USDA Aug. 2005 Fact Sheet, available at http://www.fsis.usda.gov/Fact_Sheets/BSE_Rules_Being_Strictly_Enforced/index.asp (acknowledging over 1000 "procedures" at slaughterhouses determined to be noncompliant with BSE rules between January 2004 and May 2005).

briefing in this case, which indicate that USDA's assumption that infectious BSE prions are only found in the central nervous system (primarily the brain, spinal cord, and vertebral column) is simply unjustified and not adequately protective of human health.

A study by Anne Buschmann and Martin Groschup, "Highly Bovine Spongiform Encephalopathy-Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle," published in the September 2005 *Journal of Infectious Diseases* (the "Buschmann study") (attached as Exhibit 6), contains important new information about the distribution of BSE infectivity. The Buschmann study confirmed some previous findings in rodents and other animals, but in this case the researchers were analyzing actual tissues from a cow that had been naturally infected with BSE. Testing the various tissues by exposing them to mice genetically modified to be susceptible to BSE confirmed the BSE infectivity of central nervous systems tissues. But in addition to those tissues, which USDA has assumed harbor all the infectivity in cattle, the Buschmann study demonstrated infectivity in peripheral nervous system tissues, which have not previously been considered SRMs, including the optical nerve, facial nerve, and sciatic nerve. The latter two are of particular concern because they innervate portions of cattle that are consumed by humans.

The Buschmann study directly supports arguments that R-CALF USA has already made about the inadequate scientific basis for USDA's assumption that removal of SRMs will remove virtually all risk from BSE-infected Canadian cattle. (USDA attempted to explain away the Buschmann study in the preamble to the final Japan Rule by claiming that the genetically engineered mice used in the study might not accurately reflect the progression of BSE infection in cattle. *See* 70 Fed. Reg. at 73,906. But in doing so USDA fails entirely to account for the fact that the Buschmann study produced results—using actual infected tissue from a naturally infected

cow—similar to those of other studies, for tissues where BSE prions are more highly concentrated, like the brain and spinal cord.)[10] Similar findings were also reported in August 2005 by scientists who tested various tissues from a naturally infected bovine and found evidence of BSE prions in peripheral nerves of the bovine, including the sciatic, tibial, and vagus nerves. Y. Iwamaru, *et al.*, National Institute for Animal Health (Japan), in *Prions: Food and Drug Safety*, Tetsuyuki Kitamoto, ed. (Springer 2005), abstract available at http://www.fsis.usda.gov/OPPDE/Comments/03-025IFA/03-025IFA-2.pdf. At a minimum, these studies reconfirm R-CALF USA's contention that the scientific knowledge about BSE is incomplete and evolving rapidly and, therefore, USDA cannot reasonably rely on uncertain assumptions based on studies of half a dozen years ago to assure itself and the public that the risk of Canadian imports is insignificant.[11] It also "underscores the importance" of BSE testing of cattle at slaughter "on the basis of its relevance for consumer protection." *Id.* at 941.

IV. CONCLUSION

Both law and logic dictate that R-CALF USA be provided an opportunity for argument on its motion for summary judgment and that the Court act on that motion after careful consideration

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[10] Note also that USDA misunderstood, or at least misstated, the key conclusion of the Buschmann study that it chose to disregard: "Given these factors, APHIS has determined that the finding of BSE infectivity in facial and sciatic nerves of the transgenic mice is not directly applicable to cattle naturally infected with BSE. Therefore, we do not consider it necessary to make any adjustments to the risk analysis for this rulemaking or to extend the comment period to solicit additional public comment on this issue." 70 Fed. Reg. at 73,906. The Buschmann study did not find infectivity in these peripheral nerves in transgenic mice. The peripheral nerves were harvested from a cow naturally infected with BSE. Transgenic mice were used as a bioassay model and were inoculated with peripheral nerve tissues *from an infected cow,* after which the mouse brains were examined for signs of BSE/TSE. *See* Exhibit 6 *at* 937-41.

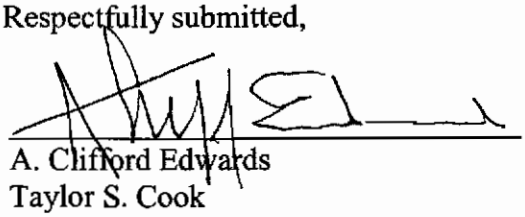
[11] Another published article of which the Court should take judicial notice, which first appeared in late June 2005, is Thomas O. McGarity, *Federal Regulation of Mad Cow Disease Risks*, 57 Admin. Law Rev. 289 (Spring 2005) (Exhibit 7). In addition to providing additional background information on the regulations and scientific and policy issues involved, the article supports many of R-CALF USA's arguments concerning the inadequacies of the Final Rule and USDA's explanation of it.

of the briefing, argument, and administrative record in this case. Developments since briefing on the cross-motions for summary judgment was concluded have only increased the support for R-CALF USA's positions and emphasized the importance of resolving its claims concerning the Final Rule. (R-CALF USA intends to focus its argument on the inadequacy of the Final Rule under the Administrative Procedure Act, rather than continuing also to pursue its claims under the National Environmental Policy Act and the Regulatory Flexibility Act.)

Therefore, R-CALF USA respectfully requests that the Court schedule, at its earliest convenience, a day of argument on the pending cross-motions for summary judgment in this case.

Dated: January 6, 2006

Respectfully submitted,



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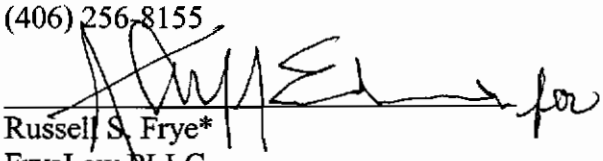

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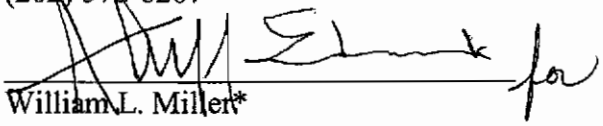

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CERTIFICATE OF SERVICE

I certify that on January 6, 2006, I served true and correct copies of the foregoing Memorandum in Support of Plaintiff's Motion To Set Motions for Summary Judgment for Argument, by first-class mail, postage prepaid on the following:

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CV-05-06-BLG-RFC
Plaintiff's Motion To Set Motions for Summary Judgment for Argument.

EXHIBIT 1
THROUGH
EXHIBIT 7

The original document is too lengthy to scan and can be viewed in the Clerk's Office.